REMARKS

Claims 1 and 28 through 49 are pending in the application.

Claim 48 has been canceled without prejudice or disclaimer to the filing of continuing applications thereon.

Reexamination and reconsideration of this application, withdrawal of all rejections, and formal notification of the allowability of the pending claims are earnestly solicited in light of the remarks which follow.

Rejection under 35 USC 112

Claim 48 stands rejected, apparently over the recited "prevention" of psoriasis. Applicants respectfully submit that the Application-as-filed clearly enables one skilled in the art to make and use the claimed embodiment without undue experimentation. However, Claim 48 has been canceled, solely to advance prosecution of the case and without prejudice or disclaimer to the filing of continuing applications thereon.

Applicants thus respectfully request withdrawal of this rejection.

The Claimed Invention is Patentable
in Light of the Art of Record

Claims 1, 28 through 36, 38, 40 through 45, 48, and 49 stand anticipated by United States Patent No. 4,250,164 to Bernstein (US 164) as evidenced by United States Patent Nos. 4,179,304 to Rossomando (US 304) and United States Patent No. 3,966,924 to Fredriksson (US 924).

Claims 37, 39, 46 and 47 stand rejected over US 164 as evidenced by US 304 and further in view of United States Patent No. 5,264,206 to Bohn et al. (US 206).

It may be useful to consider the invention as recited in the claims before addressing the merits of the rejection.

As noted in Applicants' Amendment of November 12, 2003, mass transport through a solid drug reservoir is generally considered difficult. Mass transport through a solid reservoir is considered much more difficult than diffusion through a liquid reservoir, for example, due to the restricted diffusivity provided by solid matrices.

Surprisingly, Applicants have found that a particular glucocorticoid, clobetasol propionate, can be incorporated into **stable** nail polish formulations, and that after creating a solidified film from such nail lacquer films the active ingredient clobetasol propionate is released and is able to penetrate into and through a patient's nails to provide a therapeutic dose of the drug to the underlying nail bed.

Applicants respectfully reiterate that the claimed invention is patentable in light of the cited references.

US 164 is generally directed to polishes that include topical steroids within cosmetic polishes. (Col. 2, lines 6 – 11; Col. 1, lines 47 - 50 and Col. 1, line 65 - Col. 2, line 5) US 164's preferred topical steroid is a 0.1% lotion containing betamethasone valerate, commercially available as Valisone® lotion. (Col. 1, lines 53 – 63). US 164 provides little detail as to the polish formulation, other than a "commercially available nail polish such as Revlon" may be used. (Col. 2, lines 10 – 11).

Applicants respectfully reiterate that US 164 does not teach or suggest the recited clobetasol propionate.

Nor does US 164 teach or suggest the presence of such glucocorticoids in the beneficial amounts recited in Claim 28. In contrast to the opinion urged within the Office Action, there further would have been no motivation to have selected to the recited amounts. Considered in its

entirety, US 164 expressly teaches that significantly smaller amounts of his active ingredients are "anti-psoriasis effective." The recited beneficial amounts of Claim 28 are 5 to 10 times higher than the amounts recommended by US 164. Applicants respectfully submit that "obvious to try" is not the standard for patentability.

Applicants further respectfully reiterate that even the minimal amounts of active ingredient within US 164 forms unstable compositions. Hence there most certainly would have been no motivation to have increased the amounts of US 164 to the recited levels of Claim 28, as there would have been no expectation of success.

Accordingly, Applicants respectfully reiterate that US 164 does not teach or suggest the claimed invention, considered either alone or in combination with the art of record.

The claimed invention is likewise patentable over US 304.

US 304 is merely directed to nail polishes that eliminate the toluenesulfonamide /formaldehyde resin used within conventional, e.g. purely cosmetic, nail polishes. (Col. 1, lines 42 – 45). US 304 generically states that "other ingredients" may be used to enhance "various properties" of the polish. (Col. 3, lines 8 – 11). US 304 is altogether silent as to the inclusion of pharmaceutically active ingredients, however. US 304 does expressly note the presence of both butyl acetate (b.pt. 126 °C) and either toluene or toluol (both b.pt. 110.6 °C) within its polishes, as well as "Revlon" nail polish (referenced in US 164). (Col. 1, line 67 – Col. 2, line 1; Col. 3, lines 35 – 37 and Col. 4, lines 16 - 21).

US 304, directed to conventional polishes, does not teach or suggest the recited clobetasol propionate.

And US 304 most certainly does not teach or suggest the presence of such glucocorticoids in the beneficial amounts recited in Claim 28.

Accordingly, Applicants respectfully submit that the claimed invention is patentable in light of US 304, considered either alone or in combination with the art of record.

US 924 likewise fails to teach or suggest the claimed invention.

US 924 is directed to topical ointments requiring a combination of 5-fluorouracil and corticosteroid. (Col. 2, lines 43 – 44 and Col. 1, lines 44 – 50). The topical ointments are designed for application to the skin. (Col. 2, lines 43 – 48). The 5-fluorouracil is present in amounts of up to 10%. (Col. 1, lines 58 – 61). In contrast, US 924 teaches that it is preferable to include much more moderate amounts of corticosteroid, i.e. a maximum amount of 0.1 %. (Col. 4, lines 15 – 16). Applicants respectfully reiterate that US 924 provides a laundry list of suitable corticosteroids. (Col. 1, line 62 – Col. 2, line 10).

Applicants respectfully submit that the examples to which the Office Action refers on Page 9, first full paragraph (i.e. US 924, Col. 3, line 1 - Col. 4, line 10; formulations 4 and 5) are for treating psoriasis of the skin, not nails. The corticosteroid is employed at 0.1 % and the corticosteroid of formulations 4 and 5 is either flucionolone acetonid or beta-methasone valerate, but not clobetasol propionate. As noted above, these formulations are used to treat the skin and are not nail lacquers. Applicants respectfully submit that 0.1 % of active ingredient would not work in a nail lacquer for treating psoriasis of the nails. Applicants further respectfully reiterate that there would have been no motivation to increased the amount of corticosteroid, based on the known instability of minimal amounts of active ingredient within US 164.

Accordingly, US 924, directed to preparations for skin application, does not teach or suggest the recited nail polishes.

Nor does US 924 teach or suggest such nail polishes including clobetasol propionate. US 924 merely provides an extraordinarily broad list of halogenated corticosteroids, including a list of several different categories of materials and many other specifically identified materials. US 924 does not explain why or under what circumstances one should choose any particular

halogenated corticosteroid over the other, with the exception that it expressly discloses the use of fluocinolone acetonide and beta-methasone valerate, which are altogether different from the recited clobetasol propionate.

And US 924, requiring the presence of 5-fluorouracil, further does not teach or suggest the recited nail polishes including clobetasol propionate alone as the active compound. Applicants respectfully reiterate that the recited exclusion of the required 5-fluorouracil would render US 924 unfit for its intended purpose. MPEP 2143.01 (citing *In re Gordon*, 221 USPQ 1125 (Fed. Cir. 1984)). Thus there would have been no motivation to have formed compositions including corticosteroid alone from the teachings of US 924, much less nail polishes including corticosteroid alone. There further would have been no reasonable expectation of success for compositions including corticosteroid alone, based on the teachings of US 924.

Nor does US 924 teach or suggest the incorporation of clobetasol propionate alone in the beneficial amounts recited in Claim 28. Considered in its entirety, US 924 instead expressly teaches the preferable incorporation of a maximum amount of 0.1 % halogenated corticosteroid.

There would have been no motivation to have combined US 164, US 304 and US 924. Specifically, motivation to combine prior art teachings must be found in the art, and the cited references contain no such motivation. (Alza Corp. v. Mylan Lab. Inc., No. 06-1019 (Fed. Cir. Sept. 6, 2006)

US 206 relates to nail lacquer compositions to treat mycoses of nails (antifungal compositions). Applicants respectfully submit that, in contrast to the opinion urged at Page 8, lines 1 through 2 of the outstanding Office Action, US 164 teaches lacquer compositions for treating psoriasis of the nails. However, Applicant has already demonstrated that the lacquers of US 164 are not stable and, thus, cannot be regarded as a reliable prior art teaching which the person with ordinary skill in the art would use as a starting point with a reasonable expectation of success. Considered in its entirety, US 924, the remaining reference, teaches topical compositions for treating psoriasis of the skin (i.e. not nails) requiring 5-fluorouracil in

combination with a maximum of 0.1 % flucionolone acetonid or beta-methasone valerate, which amounts would be ineffective in a nail lacquer for treating psoriasis of the nails, as noted above. Thus there is no motivation to be found in the art to combine the cited references.

However, even if combined (which Applicants did not), the present invention would not result, since at least one important feature of the claimed subject matter is missing in any such combination. US 164 teaches betamethaone valerate or fluorondrenolide mixtures containing a minimal amount of active ingredient. US 304 is merely directed to conventional nail polishes that eliminate the toluenesulfonamide/formaldehyde resin. US 924 requires 5-fluorouracil within an active ingredient mixture that is incorporated into its topical ointments.

Accordingly, even if combined, the recited nail polish including a single active ingredient would not have resulted, much less such polish whose active ingredient is clobetasol propionate alone. In contrast to the opinion urged within the Office Action, their simply would have been no motivation to have used clobetasol propionate alone in light of the express teachings of US 924, considered in its entirety. The Office Action is instead indulging in a hindsight analysis, picking elements from the cited references while ignoring other.

Nor does the combination teach or suggest the recited clobetasol propionate in the beneficial amounts recited in Claim 28, 29 and 31. The primary reference instead clearly teaches that significantly lower amounts of active ingredient are "anti-psoriasis effective." Applicants respectfully reiterate that even the minimal amount of active ingredient noted within US 164 does not form a stable composition. Thus one skilled in the art would not have been motivated to have made a "strengthened" formulation, as urged within the Office Action, as there would have been absolutely no reasonable expectation of success.

In contrast to the further urgings of the Office Action, Applicants further make of record that the glucocorticoid content of at least 8% (as recited in Claim 31) is clearly not encompassed by the cited references. Such advantageous glucucorticoid amounts instead exceed US 924 by

over 50%. In fact, the advantageous glucucorticoid amount of Claim 31 is 80 times greater than US 924's recommended amount of 0.1%.

Accordingly, Applicants respectfully submit that the claimed invention is patentable in light of US 164, US 304 and US 924, considered either alone or in combination.

Claims 37, 39, 46 and 47 are likewise patentable in view of US 206.

US 206 patent is directed to nail lacquers containing at least one water insoluble film-former and at least one antimycotic agent. (Col. 2, lines 58 – 63).

US 206 does not teach or suggest the inventive nail polishes incorporating the recited clobetasol propionate.

US 206 thus can not teach or suggest the inventive nail polishes incorporating the recited clobetasol propionate and the advantageous film-forming agents of Claims 37 through 39 or additives of Claim 46 and 47.

Accordingly, Applicants respectfully submit that the claimed invention is patentable in light of US 206, considered either alone or in combination with the remaining art of record.

Again, there would have been no motivation to have combined these references.

However, even if combined (which Applicants submit should not be done), the present invention would not result.

In particular, the combination would not result in the recited inventive nail polishes incorporating clobetasol propionate alone.

Thus the combination can not teach or suggest the inventive nail polishes incorporating the recited clobetasol propionate and the advantageous film-forming agents of Claims 37 through 39 or additives of Claim 46 and 47.

Accordingly, Applicants respectfully submit that the claimed invention is patentable in light of US 206, considered either alone or in combination with US 164, US 304 and US 924.

CONCLUSION

It is respectfully submitted that Applicant has made a significant and important contribution to the art, which is neither disclosed nor suggested in the art. It is believed that all of pending Claims 1 and 28 through 49 are now in condition for immediate allowance. It is requested that the Examiner telephone the undersigned if any questions remain to expedite examination of this application.

It is not believed that extensions of time or fees are required, beyond those which may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time and/or fees are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required is hereby authorized to be charged to Deposit Account No. 50-2193.

Respectfully submitted,

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